

REMARKS

Status of the Application

Claims 1 and 69-81 are currently pending. Claims 2-68 have been previously deleted. In this Amendment, claims 75-80 have been canceled in response to a restriction requirement. Applicants reserve the right to pursue these claims in one or more divisional applications.

Claims 1 and 69 have been amended to remove the language “and homologues and analogues thereof”. No new matter has been added as a result of these amendments.

Specification

The Examiner says that the specification is objected to because of the use of trademarks disclosed throughout the specification and that not all of them are capitalized or accompanied by generic termination. The Examiner specifically notes the use of PCR™ on page 54. Applicants thank the Examiner for catching these issues with respect to the trademarks. Applicants have amended the specification to correct this issue. However, Applicants have checked and believe that PCR is not a trademark. If the Examiner believes differently, Applicants would appreciate receiving clarification from the Examiner. In view of these amendments, this objection should be withdrawn.

The specification has also been objected to because the priority information has not been updated. Applicants also thank the Examiner for raising this point. In response to this objection, Applicants have updated the priority information with respect to this application. In view of these amendments, this objection should be withdrawn.

Sequence Compliance

The Examiner says that the application fails to comply with the requirements of 37 CFR 1.821 through 1.825, specifically, the Examiner says that to be in compliance, Applicants are required to identify all amino acid sequences of at least 4 L-amino acids and at least 10 nucleotides by a sequence identifier. The Examiner says that the specification discloses sequences that have not been identified by a sequence identifier, namely on page 40, Example 1, Example 2 (page 42), pages 43-48 and 51. Applicants herewith enclose a new Sequence Listing as requested by the Examiner. Applicants have also amended the above pages to include the requisite sequence identifier. A statement regarding the Sequence Listing is also enclosed. In view thereof, this rejection should be withdrawn.

Information Disclosure Statement

Applicants thank the Examiner for entering the Information Disclosure Statement filed on October 1, 2004. Applicants also thank the Examiner for noting that the reference “SCRIP 2120:21 (4/16/96)” was crossed out. Applicants herewith submit a revised PTO 1499 form containing the correct citation for the

above reference. Applicants respectfully request that the Examiner initial the enclosed 1449 form and return it to the Applicants at the Examiner's earliest convenience.

Rejection of claims under 35 U.S.C. Section 112, First Paragraph

Claims 1, 69-74 and 81 are rejected under 35 U.S.C. Section 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner says that the specification fails to provide any "additional" representative species of the claimed genus to show that Applicants were in possession of the claimed genus. According to the Examiner, "[A] representative number of species means that the species, which are adequately described are representative of the entire genus." Applicants respectfully traverse.

As a preliminary matter, Applicants would like to point out that the phrase "and homologues and analogues thereof" have been deleted from claims 1 and 69, thereby reducing the size of the claimed genus.

As discussed in the *MPEP* Section 2163.04, the inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. Specifically, this section of the *MPEP* states:

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Id*

Applicants respectfully submit that the Examiner has not met his burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in Applicants' specification a description of the invention as defined by the claims as currently amended. Applicants submit that the specification provides an adequate written description that is commensurate with the scope of the claims as currently amended. Specifically, Applicants believe that the specification provides a description of a representative number of species of the claimed genus to demonstrate that Applicants were in possession of the claimed genus. For example, the specification on page 14, beginning at line 11 – page 15, line 13, describes a number of different species of the claimed invention having the structure "B-C-X". Additionally, the specification on page 15, lines 14-16 describes a species of the claimed invention having the structure "A-C-Y". Moreover, the specification on page 15, lines 17-20, describes a species of the claimed invention having the structure "A-C-X-Y". Still further, the specification on page 15, lines 20-24, describes a species of the claimed invention having the structure "A-B-C-Y". Still further, the specification on page 15, line 30 –

page 16, line 12, describes a number of different species of the claimed invention having the structure "A-B-C-X-Y". Still further, the specification on page 16, lines 13-16 a species having the general structure A-B₁-C₁-X₁-Y where B₁ and X₁ is absent. In addition, Examples 1-13 describe in detail how to make compounds encompassed by claims 1 and 69. Thus, based on the above description contained in Applicants' specification, one skilled in the art would clearly recognize a description of the invention as defined by the currently pending claims. In view thereof, this rejection is now moot and should be withdrawn.

Claims 1, 69-74 and 81 are rejected under 35 U.S.C. Section 112, first paragraph as not being enabled for any homologue or analogue. According to the Examiner, the amount of experimentation required to practice the claimed invention is undue as the claims encompass an unspecified amount of homologues and analogues of the claimed protein and the claims do not establish any functional limitations to demonstrate a correlation of structure and function. Applicants respectfully traverse.

While not agreeing with the Examiner's rejection, in order to expedite prosecution, claims 1 and 69 have been amended to delete the phrase "and homologues and analogues thereof". In view of the deletion of this phrase from the claims, Applicants submit that the specification is adequately enabled and that this rejection is now moot and should be withdrawn.

REQUEST FOR RECONSIDERATION

Reconsideration and withdrawal of all claim rejections are respectfully requested. Applicants believe that the present application is in condition for allowance. Should the Examiner have any questions or would like to discuss any matters in connection with the present application, the Examiner is invited to contact the undersigned at

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